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FORM**

(to be used for all correspondence after initial filing)

Application Number **09/780,990**Filing Date **February 9, 2001**First Named Inventor **Richard H. PETERS**Art Unit **1616**Examiner Name **Sabiha Naim QAZI**Mail Stop **AF**Attorney Docket Number **8500-0258****RECEIVED****DEC 04 2001****TECH CENTER 1600 2900****ENCLOSURES (Check all that apply)**

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| <input checked="" type="checkbox"/> No fee due   | <input type="checkbox"/> Drawing(s)  | <input type="checkbox"/> After Allowance Communication to a Technology Center (TC)      |
| <input type="checkbox"/> Fee(s) due  | <input type="checkbox"/> Licensing-related Papers  | <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences     |
| <input type="checkbox"/> Fee Transmittal   | <input type="checkbox"/> Petition  | <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) |
| <input type="checkbox"/> Check for \$0   | <input type="checkbox"/> Petition to Convert to a Provisional Application                | <input type="checkbox"/> Proprietary Information  |
| <input checked="" type="checkbox"/> Charge any underpayment or credit any overpayment to Deposit Account No. 18-0580 | <input type="checkbox"/> Power of Attorney, Revocation, Change of Correspondence Address | <input type="checkbox"/> Status Letter  |
| <input checked="" type="checkbox"/> Return postcard  | <input type="checkbox"/> Terminal Disclaimer   | <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):         |
| <input type="checkbox"/> Amendment/Reply   | <input type="checkbox"/> Request for Refund  | <u>Request for Reconsideration</u>  |
| <input type="checkbox"/> After Final   | <input type="checkbox"/> CD, Number of CD(s):  |   |
| <input type="checkbox"/> Affidavits/declaration(s)   |  |   |
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| <input type="checkbox"/> Express Abandonment Request   |  |   |
| <input type="checkbox"/> Information Disclosure Statement & Form(s) PTO-1449   |  |   |
| <input type="checkbox"/> Copy(ies) of cited reference(s)   |  |   |
| <input type="checkbox"/> Certified Copy of Priority Document(s)  |  |   |
| <input type="checkbox"/> Response to Missing Parts / Incomplete Application  |  |   |
| <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53   |  |   |

## Remarks:

**The Commissioner is hereby authorized to charge any additional or underpayment of fee(s) to Deposit Account No. 18-0580.**

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm or Individual Name (print/type)	Mark L. Warzel (Reg. No. 47,264) Reed & Egerle LLP	Telephone	(650) 330-0900
Signature		Date	November 24, 2003

**CERTIFICATE OF TRANSMISSION/MAILING**

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Name (print/type)	Mary O'Malley		
Signature		Date	November 24, 2003



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

The Application of:

Richard H. PETERS et al.

Confirmation No.: 2254

Serial No.: 09/780,990

Group Art Unit: 1616

Filing Date: February 9, 2001

Examiner: Sabiha Naim QAZI

Title: SYNTHESIS OF ANTI-ESTROGENIC AND OTHER THERAPEUTIC STEROIDS FROM 21-HYDROXY-19-NORPREGNA-4-EN-3-ONE

REQUEST FOR RECONSIDERATION

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Sir:

In response to the Final Office Action for the subject patent application mailed on March 21, 2003 and the Advisory Action mailed on August 14, 2003, and further to the Notice of Appeal filed on September 22, 2003, applicants respectfully request consideration of the following remarks:

REMARKS

This response is being filed (1) to clarify the status of the claims amendments following the Advisory Action mailed August 14, 2003; (2) to make of record a summary of telephone discussions between the undersigned and the Examiner following the issuance of the Advisory Action; and, (3) pursuant to the Examiner's Request, to provide a Request for Reconsideration that further traverses the remaining grounds for rejection of the claims.

**Claims Status and Summary of Telephone Discussions:**

In the Advisory Action dated August 14, 2003, it is not clearly indicated on the Advisory Action front page whether or not the Amendment filed July 21, 2003 has been entered. For example, although box 2 and box 7a on the form have not been checked (to thereby indicate, if checked, that the Amendment would not be entered), there is no statement indicating that the Amendment has been or will be entered. However, the continuation of the comments provided by the Examiner for box 5 at page 2 of the Action, does refer to the "amended claims," implying that the Amendment has been entered.

To clarify the status of the claims amendments, telephone discussions between the undersigned and Examiner Qazi were conducted on August 28 and September 4, 2003. In those discussions, Examiner Qazi confirmed that the Amendment filed July 21, 2003 has been entered.

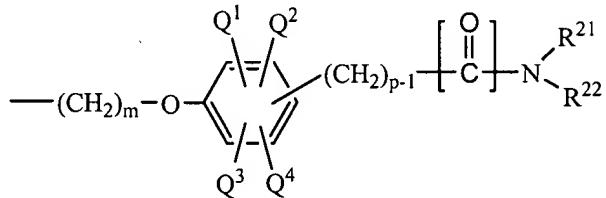
Claims 14-21, 37 and 41 therefore remain under consideration as amended according to the Amendment filed July 21, 2003. The remaining claims, i.e., claims 1-13, 19, 20, 22-36, 38-40 and 42-44 stand withdrawn from consideration as being directed to a non-elected invention.

**Double Patenting Rejections:**

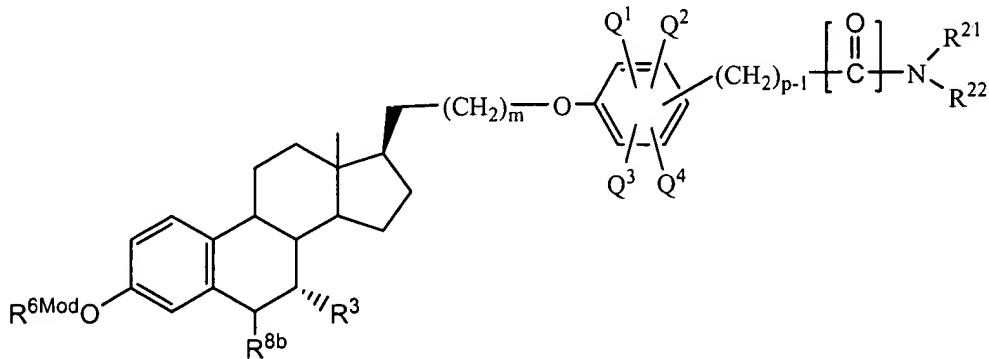
In the Final Office Action mailed March 21, 2003, the double patenting rejections have been stated as being maintained; however, the Advisory Action mailed August 14, 2003 does not indicate whether these rejections have been withdrawn or maintained. Applicants therefore request that the Examiner kindly provide a statement as to whether the double patenting rejections have been withdrawn. Should the Examiner consider the double patenting rejections to be maintained, applicants respectfully request reconsideration for at least the following reasons.

Claims 14, 15, 21, 37 and 41 have been rejected for obviousness-type double patenting as allegedly being unpatentable over claims 1-16 of U.S. Patent No. 6,281,205 and claims 7-25 of U.S. Patent No. 6,054,446. Applicants respectfully traverse these rejections for at least the following reasons.

Each of independent claims 14 and 21 recite that each of R<sup>8a</sup> and R<sup>8b</sup>, respectively, is an oxo group (i.e., a oxygen double-bonded to a ring carbon atom). (Please note that the subscript "t" in the chemical formulae of former claims 14 and 21 has been previously deleted for simplicity). In other words, applicants' claims recite that R<sup>20</sup> in the formula of claim 14 may be



while claim 21 recites a compound having the structural formula (VII):



Each of these formulae include the presence of a carbonyl group (i.e., "t" is unity) next to the terminal substituted amino group. The cited claims of each of U.S. Patent Nos. 6,281,205 and 6,054,446, however, do not include such a carbonyl group. Applicants' claims are therefore not obvious over the cited claims of these patents.

For at least the foregoing reasons, withdrawal of the double patenting rejections is in order and is requested.

**Rejections Under 35 U.S.C. §102 and/or §103:**

Claims 14-16, 18, 21, 37 and 41 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by or, in the alternative, under 35 U.S.C. §103(a) as allegedly obvious over Tanabe et al (WO 99/33859, hereinafter "Tanabe"). Applicants respectfully traverse these rejections for at least the following reasons.

In the Advisory Action, it is stated that the "amended claims are still considered obvious. Substituents containing a methyl or an ethyl group (H, and hydrocarbyl claimed) would have been obvious . . . because they differ by only one or two carbon atoms." Applicants respectfully but strongly disagree that their claims are properly rejected for this reason.

As noted above, each of independent claims 14 and 21 have been previously amended to recite that each of the substituents R<sup>8a</sup> and R<sup>8b</sup>, respectively, is an oxo group. Applicants submit that these prior amendments obviate the rejections based upon Tanabe.

More particularly, Tanabe discloses generic formulae (I), (II) and (III) at pages 17, 20 and 21, respectively, in which the substituent R<sup>8</sup> is located in the same ring position as applicants' substituents R<sup>8a</sup> and R<sup>8b</sup>. Tanabe defines R<sup>8</sup>, however, as being selected from a Markush group "consisting of hydrogen, hydroxyl, -NO<sub>2</sub>, -CHO, -CH<sub>2</sub>CH=CH<sub>2</sub>, -NR<sup>16</sup>R<sup>17</sup>, and -(CH<sub>2</sub>) NR<sup>16</sup>R<sup>17</sup> wherein R<sup>16</sup> and R<sup>17</sup> may be the same or different and are either hydrogen, lower alkyl or acetyl". Preferably R<sup>8</sup> is hydrogen.

Applicants' R<sup>8a</sup> and R<sup>8b</sup> substituents, however, are oxo groups, that is, only oxygen is double-bonded to a ring carbon atom. Such an oxygen substituent is not taught or suggested by Tanabe. No motivation or reason is provided by Tanabe to utilize such oxo substituents, nor is there any apparent discussion of the preparation of compounds according to applicants' claims having an oxygen substituent in this ring position. Tanabe therefore fails to anticipate or render *prima facie* obvious the present claims.

Applicants further submit that it is not obvious to substitute an oxo group for Tanabe's R<sup>8</sup> substituent selected from a Markush group "consisting of hydrogen, hydroxyl, -NO<sub>2</sub>, -CHO, -CH<sub>2</sub>CH=CH<sub>2</sub>, -NR<sup>16</sup>R<sup>17</sup>, and -(CH<sub>2</sub>) NR<sup>16</sup>R<sup>17</sup>." In particular, the reliance upon homology to reject the claims (as appears to be suggested in the Advisory Action) is not a proper basis for rejection of applicants'

claims at least for the reason that an oxo group substituent is not a homolog of the substituents mentioned by Tanabe.

In addition, the obviousness of structural similarity has been addressed in the MPEP at §2144.09 (page 2100-152, 8<sup>th</sup> ed.) based upon *In re Hoeksema*, 399 F.2d 269, 274-75, 15 USPQ 597, 601 (CCPA 1968), as follows:

[i]f the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public. In this context, we say that the absence of a known or obvious process for making the claimed compounds overcomes a presumption that the compounds are obvious, based on the close relationships between their structures and those of prior art compounds.

In the present case, Tanabe fails to disclose or suggest both the claimed compounds and a method of making them. As such, consistent with this section of the MPEP, applicants' claims are both novel and non-obvious.

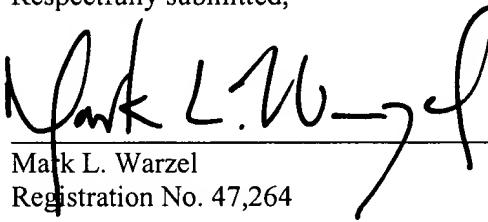
For at least the foregoing reasons, the present claims are patentable over Tanabe et al (WO 99/33859). Withdrawal of the outstanding rejections based upon Tanabe et al is requested.

The present application and claims are believed to be in condition for allowance. A notice to that effect is earnestly solicited.

If the Examiner has any questions regarding this response or the application in general, the Examiner is invited to contact the undersigned by phone at (650) 330-4908.

Respectfully submitted,

By:

  
Mark L. Warzel  
Registration No. 47,264

Date: November 24, 2003

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